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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,667	01/13/2004	Hiroshi Maeda	Q79414	9625
23373	7590	08/09/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			WHITE, EVERETT NMN	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,667

Applicant(s)

MAEDA ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Duplicate Claims

1. Applicant is advised that should claims 1-6 and 13-24 be found allowable, claims 7-12 and 25-36 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 7, 13, 14, 21, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al (US Patent No. 6,383,344).

Applicants claim a process for producing a saccharide having a lowered molecular weight, which comprises at least a step of irradiating an electron beam to a polysaccharide fraction. Additional limitations in the dependent claims include the process wherein the polysaccharide fraction to which the electron beam is irradiated is a glycosaminoglycan fraction; the process wherein the glycosaminoglycan fraction is a fraction comprising at least one species of glycosaminoglycans which may be selected as hyaluronic acid; the process wherein the hyaluronic acid fraction to which the electron beam is irradiated has a weight average molecular weight of 5,000 to 3,000,000 (Da); and the process wherein the electron beam is irradiated at a dosage of 5 to 400 (kGy).

The Miller et al patent discloses a method for reducing the molecular weight of a polymer that comprises subjecting a solid phase polymer to a dose of gamma

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irradiation sufficient to permit the desired molecular weight reduction to occur (see abstract). See column 3, lines 6-8 of the Miller et al patent wherein the polymer thereof may be a polysaccharide polymer, preferably hyaluronic acid. Miller et al also discloses that typically, the dosage of irradiation used will vary from about 1 kGy to about 120 kGy (see the paragraph bridging columns 2 and 3), which covers part of the range of the dosages set forth in instant Claim 14. Miller et al discloses that the hyaluronic acid thereof comprises an initial molecular weight in the range of from about 1,000 kdaltons to about 3,000 kdaltons (see column 3, lines 6-10), which covers part of the range of the molecular weight set forth in instant Claims 14, 21 and 26. The method disclosed in the Miller et al patent anticipates the instantly claimed process for producing a saccharide having a lower molecular weight.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al (US Patent No. 6,383,344).

Applicants claim a process for producing a saccharide having a lowered molecular weight, which comprises at least a step of irradiating an electron beam to a polysaccharide fraction. Additional limitations in the dependent claims include the process wherein the polysaccharide fraction to which the electron beam is irradiated is in a solid state and the electron beam is irradiated at a dosage which satisfies an equation; the process wherein the polysaccharide fraction to which the electron beam is irradiated is a glycosaminoglycan fraction; the process wherein the glycosaminoglycan fraction is a fraction comprising at least one species of glycosaminoglycans selected from the group consisting of hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratin sulfate, heparan sulfate and heparin; the process wherein the hyaluronic acid fraction to which the electron beam is irradiated has a weight average molecular weight of 5,000 to 3,000,000 (Da) and is in a solid state, and the electron beam is irradiated at a dosage of 5 to 400 (kGy).

The Miller et al patent discloses a method for reducing the molecular weight of a polymer that comprises subjecting a solid phase polymer to a dose of gamma irradiation sufficient to permit the desired molecular weight reduction to occur (see abstract). See column 3, lines 6-8 of the Miller et al patent wherein the polymer thereof may be a polysaccharide polymer, preferably hyaluronic acid. The Miller et al patent discloses that the type and dosage of the irradiation that can be employed in the practice of their invention will vary depending on the type of polymer treated, the degree of molecular weight reduction desired, and the form of the polymer, i.e. whether the polymer is in the form of a salt. Miller et al discloses that the preferred type of irradiation is gamma irradiation and Miller et al also discloses that typically, the dosage of irradiation used will

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vary from about 1 kGy to about 120 kGy (see the paragraph bridging columns 2 and 3), which covers the total range or part of the range of the dosages set forth in instant Claims 14-18, 22-24, 26-30 and 34-36. Miller et al discloses that the hyaluronic acid thereof comprises an initial molecular weight in the range of from about 1,000 kdaltons to about 3,000 kdaltons (see column 3, lines 6-10), which covers the total range or part of the range of the molecular weight set forth in instant Claims 14-24 and 26-36. Also see column 4, lines 21-25 of the Millet et al patent wherein the polymers thereof are treated in the solid phase prior to and during treatment, which embraces the solid state irradiation recited in instant Claims 2 and 8. The instant claims differs from the Miller et al patent by claiming irradiated dosages that are outside of the range of the irradiated dosages used for the polysaccharide fractions or hyaluronic acid recited in some of the claims. However, the Miller et al patent shows that the basis process of irradiating polysaccharide or hyaluronic acid at a particular dosage is known in the art. It is within the skill of an artisan in this art to adjust the dosage of electron beam in order to achieve optimum operation of the process. One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to subject a polysaccharide or hyaluronic acid to a particular irradiated dosage in the process of the Miller et al patent to obtain a polysaccharide or hyaluronic acid of lower molecular weight in view of their closely related structures and the resulting expectation of similar reduction properties.

Summary

6. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

7. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.


E.White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600